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Registration Decision RD2013-09

Ammonia (Present as Ammonium Sulphate)

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Registration Decision for Ammonia (Present as Ammonium Sulphate)

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of BCMW Technical and Busan 1215 Liquid Microbicide, containing the technical grade active ingredient ammonia (present as ammonium sulphate), to control algal, bacterial and fungal deposits in influent water systems, and all process water systems used for the manufacture of paper and paperboard products.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-15, *Ammonia (Present as Ammonium Sulphate)*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Ammonia (Present as Ammonium Sulphate) and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-15. This decision is consistent with the proposed registration decision stated in PRD2012-15.

For more details on the information presented in this Registration Decision, please refer to PRD2012-15, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Ammonia (Present as Ammonium Sulphate)?

Ammonium sulphate is an inorganic salt providing a source of ammonia (NH_3). The active ingredient resulting from Busan 1215 Liquid Microbicide treatment is monochloramine (NH_2Cl), which is being generated when the ammonia from the ammonium sulphate reacts with the sodium hypochlorite. This reaction occurs through a chemical feed skid mixing sodium hypochlorite and Busan 1215 Liquid Microbiocide. Monochloramine is known to kill cells by oxidation reactions with membrane-bound enzymes.

Health Considerations

Can Approved Uses of Ammonia (Present as Ammonium Sulphate) Affect Human Health?

Ammonia (present as ammonium sulphate) is unlikely to affect human health when used according to label instructions.

Exposure to ammonia (present as ammonium sulphate) may occur when handling the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Ammonia (present as ammonium sulphate) is of low toxicity by the oral, dermal and inhalation routes, minimally irritating to the eyes, slightly irritating to the skin, and is not a dermal sensitizer. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects. The precautionary label statement indicating that contact with skin, eyes, and clothing must be avoided, and the personal protective equipment statement that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear are effective mitigative measures to reduce the risk associated with the use of this product.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use of Busan 1215 Liquid Microbicide is for treatment of process waters in the production of non-food contact paper. Dietary intake is not anticipated.

No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Busan 1215 Liquid Microbicide

Occupational exposure to individuals loading Busan 1215 Liquid Microbicide is not expected to result in unacceptable risk when the product is handled according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Ammonia (Present as Ammonium Sulphate) Is Introduced Into the Environment?

BCMW Technical and the associated end-use product, Busan 1215 Liquid Microbicide, are to be used in industrial process water systems for the control of slime. The product is applied in conjunction with sodium hypochlorite to form monochloramine, a slow acting oxidizing microbicide. Monochloramine, which is the primary chemical of environmental concern with the use of Busan 1215, could potentially enter the environment through industrial effluent discharge. Discharges can be to both freshwater and marine water bodies, as industrial facilities where this product is to be used can be located near both types of aquatic environments. Levels of monochloramine discharged to the environment through effluent is expected to be low; however, the chemical is toxic to aquatic organisms, and label statements referring to dechlorination of effluent to undetectable levels will be required prior to discharge, where applicable.

Value Considerations

What Is the Value of Busan 1215 Liquid Microbicide?

Busan 1215 Liquid Microbicide is used for the control of bacterial, fungal and biofilm growth in recirculating cooling water systems, evaporative condensers, airwashers, reverse osmosis systems, influent water systems and industrial fresh water systems such as holding ponds used for cooling purposes, and in process water systems used for the manufacture of paper and paperboard products.

Busan 1215 Liquid Microbicide will provide a source of ammonia to be mixed with sodium hypochlorite to generate monochloramine. Because of its specific chemical properties, this new active ingredient provides an alternative for the treatment of free floating bacteria, fungi and biofilms in fouled industrial systems. Monochloramines are less corrosive for the system and less reactive with organic matter than stronger oxidizers. As a consequence, the product is not expected to have an impact on chemical additives (for example, optical brightening agents) used in pulp treatment.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Busan 1215 Liquid Microbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because ammonia (present as ammonium sulphate) is used for formulating a commercial product, the statement on the technical label: "prevent access by unauthorized personnel" in the precaution section of the technical label will help mitigate the inappropriate use of the product and help avoid accidental exposure. Other precautionary statements on the technical and end-use product labels, such as: "Avoid breathing vapor. Avoid contact with eyes, skin, clothing, and the contamination of food. Wear coveralls over long sleeved shirt and long pants, goggles or face shield, chemical-resistant gloves, socks and chemical-resistant footwear during mixing, loading, application, clean-up and repair activities." should be effective in minimizing the potential for exposure.

Environment

Label statements necessitating dechlorination of effluent to non-detectable levels when monochloramine residuals (measured as chlorine, Cl_2) are detected prior to discharge will be required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-15, *Ammonia (Present as Ammonium Sulphate)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.